REMARKS

Election:

Applicant affirms the election of claims 1-33, which describe surgical connection apparatus, and requests examination of these claims. Claims 4-5, 12-16, 18 and 33 have been amended to correct typographical errors. Claims 34-40 stand withdrawn from consideration.

Applicant reserves the right to file continuation or divisional applications directed to the withdrawn claims.

Section 103 Response:

Claims 1-33 were rejected under 35 U.S.C. §103(a) as being unpatentable over Arcia, et al. (U.S. 6,358,258) (hereafter "Arcia") in view of Miller, et al. (U.S. Patent No. 6,709,442) (hereafter "Miller").

Applicant submits that since the rejection does not (1) explain what elements in Arcia are to be modified, (2) explain how the proposed modification would be carried out, or (3) properly identify barbs in either reference, a prima facie case of obviousness has not been established. A detailed discussion is provided below.

Claim 1 recites:

> Surgical connection apparatus comprising:
> a support structure;
> a plurality of self-closing clips, each clip being releasably coupled to said support structure; and
> a plurality of barbs, each barb being coupled to said support structure, said barbs being separate from said clips, which are ejectable from said support structure independently of said barbs.

In the Office Action, it was stated that Arcia discloses an anastomosis device 200 comprising support structure 210 and needles 270 or barbs (unidentified) slidably coupled to channels or tubular members 240 and 250 so

that that needles 270 or barbs (unidentified) support graft G and deploy suture 272 to secure the graft to a vessel.

It was then advanced that Miller shows self-closing shape memory clips 10, 236 slidably disposed in tubes 51, 230 to conclude that:

> it would have been obvious "to incorporate the device of Miller for delivery the clip or clips independently from the barb or barbs into the device, as disclosed by Arcia in order to gain the advantages of using shape memory clip wherein after the fastener or clip is deployed through layers of tissue the clips assume a shape that automatically applies to the layers of tissue an appropriate hemostatic compression which is relatively independent of tissue thickness, the fastener or clip is a suitable replacement for connection non-bio-absorbable sutures and staples in certain clinical application as suggested by Miller (see col. 3, lines 54-64) while the graft holding technique of Arcia still maintains because it is more superior than the graft holding technique of Miller."

First, neither reference discloses both clips and barbs. Therefore, the combination of Arcia and Miller does not suggest the claimed clip and barb combination.

Further, the assertion that "it would have been obvious to incorporate the device of Miller for delivery the clip or clips independently from the barb or barbs into the device, as disclosed by Arcia" is not understood. Applicant submits the Office Action does not set forth what "device of Miller" is to be incorporated into Arcia or how that is to be done. Applicant also submits that contrary to what is asserted in the Office Action, Arcia does not disclose a clip. Flexible needles 270 do not form a clip. Suture 272, which is attached to the needle, is used to suture the tubular vessels together.

Further, there is no incentive to incorporate Miller's spring shaped fasteners into Arcia. For example, Arcia's suture can be tied into a loop to secure the graft to a second body duct. But no explanation of how Miller's fastener configuration would provide a similar loop to secure the two tubular members together has been provided.

Applicant also submits that the argument that Miller states that the Miller

fastener is a suitable replacement for conventional non-bioabsorbable suture and staples in certain clinical applications is incomplete because no explanation why Miller's spring shaped fastener would be a suitable replacement for Arcia's loop forming suture in Arcia's application has been made. And the accompanying assertion that such a replacement should be made, while the graft holding technique is maintained because it is more superior than the graft holding technique of Miller is improper. This argument is not only not understood, it is not supported in the references and appears to render the rejection to be nothing more than impermissible hindsight application of the teachings of Applicant's invention. There must be some concrete evidence in the record to support a position of obviousness. If the Examiner is relying on personal knowledge, Applicant respectfully requests an affidavit that provides citations for support.

Applicant further submits the Arcia embodiment illustrated in figures 8-14 and referenced in the Office Action does not teach deploying needles and sutures though channels 240 and 250 to secure the graft to a vessel because the suture guide channels in the illustrative embodiment cited in the Office Action are inoperative or not enabled for this purpose. Arcia states that the suture device guide channel has a first portion 240 and a second portion 250, which according to the specification (col. 9, lines 24-26) may be integrally formed in shaft structure 220 or they may be individual tubular structures. These channels are supposed to guide needles along a path similar to that shown in figure 1B where each path first passes the needle radially into and out of the end of the first body duct and into the hole of the second body duct (see col. 9, lines 16-39 and col. 6, lines 24-50). With reference to figure 11, it is stated that the first portion 240 is located on an outer side of the graft body duct G and has an opening 241 positioned to open towards the graft body duct G. The needle 270 passes from the first body portion 240 through the wall of graft G and into the second portion 250 of the guide channel located on the inner side of the graft (col.10, lines 2-7). However, there is no description of or a drawing showing how the second guide channel portion 250 is supported inside the graft or coupled to first guide portion

240 or to shaft structure 220 to form such a path. That is, no structure has been described to enable positioning second guide portion 250 inside the graft as shown in figure 11. Accordingly, Arcia should not be relied on as teaching deploying needles and sutures though channels to secure the graft to a vessel.

In sum, Arcia does not disclose a plurality of self-closing clips and a plurality of barbs being separate from the clips, let alone clips that are ejectable from the support structure independently of the barbs as set forth in claim 1. Arcia's embodiment illustrated in figures 8-14 at most discloses flexible needles having a suture "attached" thereto such that a flexible needle-suture pair can be ejected together. Thus, Arcia does not disclose separate clips and barbs as set forth in claim 1.

Miller does not make up for this deficiency because Miller merely discloses delivering spring shaped clips (e.g., clips 10) or suture element 236 through a tube. Even if Miller's clips were formed from memory shape material, this does not necessarily mean that they are self-closing clips. Further, Miller does not disclose a surgical connection apparatus that includes barbs and clips. Therefore, Miller does not provide (1) any reason to add barbs to Arcia, (2) how barbs would be incorporated into Arcia, (3) any reason to incorporate self-closing clips into Arcia, or (4) how self-closing clips would be incorporated into Arcia.

Finally, Arcia does not disclose an operative embodiment of deploying needles and sutures though channels to secure the graft to a vessel in figures 8-14 as discussed above, and therefore does not teach deploying needles and sutures through channels to secure the graft to a vessel and Miller does not remedy this deficiency.

In view of the foregoing, claim 1 and all claims that depend therefrom are allowable.

Claim 17 recites:

> Surgical connection apparatus comprising:
> a support structure forming a first plurality of paths and a second plurality of paths;

> a plurality of clips, each clip being slidably disposed in one path of said first plurality of paths; and
> a plurality of barbs, each barb being slidably disposed in one path of said second plurality of paths.

Arcia does not disclose a plurality of clips and barbs, let alone the paths associated therewith as set forth in claim 17. Arcia at most discloses flexible needles having a suture "attached" thereto, where each flexible needle and suture pair are in the same path. Miller also does not disclose this combination of elements and no reason to modify Arcia to include these features has been provided. Therefore, claim 17 and all claims that depend therefrom are allowable.

Claim 22 recites:

> Surgical connection apparatus for connecting a first structure to a second structure, said connection apparatus comprising a support structure, a plurality of barbs coupled to said support structure, a plurality of clips being slidably coupled to said support structure and unattached to said barbs; means for moving said barbs; and means for ejecting said clips from said support structure.

Arcia does not disclose a plurality of barbs and plurality of clips being unattached to the barbs as set forth in claim 22. Arcia at most discloses flexible needles having a suture "attached" thereto. Miller also does not disclose this combination of elements and no reason to modify Arcia to include these features has been provided. Therefore, claim 22 and all claims that depend therefrom are allowable.

Claim 28 recites:

> Surgical connection apparatus for connecting a first structure to a second structure, said connection apparatus comprising a support structure, a plurality of barbs coupled to said support structure, a plurality of clips being slidably coupled to said support structure and unattached to said barbs; and means for simultaneously ejecting said plurality of clips.

Arcia does not disclose a plurality of barbs and a plurality of clips being unattached to the barbs as set forth in claim 28. Arcia at most discloses flexible

needles having a suture "attached" thereto. Miller also does not disclose this combination of elements and no reason to modify Arcia to include these features has been provided. Therefore, claim 28 and all claims that depend thereform are allowable.

Discussion of the dependent claims under this rejection is not necessary at the present time. However, Applicant submits that the dependent claims contain allowable subject matter as well.

If the Examiner maintains any of the foregoing rejections, Applicant requests that the Examiner clearly point to specific examples in the cited references that support any rejection so maintained.

CONCLUSION

Applicant submits that the pending claims are in condition for allowance and respectfully requests the issuance of a formal Notice of Allowance at an early date. If a telephone interview would advance prosecution of the application, the Examiner is invited to telephone the undersigned at the number provided below.

In the unlikely event that the transmittal letter is separated from this document and/or the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due, including additional claims fees, in connection with the filing of this document to Deposit Account No. 13-2546 referencing Attorney Docket No. P-22022.00.

Respectfully submitted,

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